

U.S. Application No.: 09/438,759
AMENDMENT B AND REQUEST FOR TELEPHONE INTERVIEW

Attorney Docket: 2368/098

adapted for guiding the catheter for introduction into the proximal end of the cannula tube (10), and

a connector (22, 24, 26) electrically connected to the cannula tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said cannula tube (10) has an electrically insulated outer covering extending from the body part (18) out to the sharp tip (14) and which leaves the sharp tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the cannula tube (10);

wherein the distal tip (14) of the cannula tube (10) is a facet cut (12).

REMARKS

Review and reconsideration of the Office Action of August 13, 2002 is respectfully requested in view of the above amendments and the following remarks.

Claims 12 and 19 have been amended. Claim 12 has been amended by adding the limitations of "a sharp tip" and "steel tube". Support for claims amendment can be found in Figure 2, element 16, Claim 23, and page 5, lines 15-16, of the specification.

Claim 19 has been re-written in independent form.

Care has been taken to ensure that no new matter is added to the claims.

Applicants reviewed the Schaer reference and note that

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compared with amended Claim 12, the reference fails to teach: 1) a cannula; 2) an electrically conductive cannula tube formed by a steel tube; 3) a sharp tip; and 4) the tip is exposed at least in its distal end area

The cannula, according to the present invention, is a cannula tube that is used to pierce a tissue. Therefore, it is necessary that the cannula is rigid and has got a sharp piercing tip. After the tissue and the nerve area are penetrated by the rigid cannula with the sharp tip, the position of the tip is verified by electro stimulation. If the position of the tip of the cannula is correct, the flexible catheter is introduced through the cannula into the nerve sheath or the spinal channel where the flexible catheter can be advanced without any resistance.

The cited reference teaches a catheter.

According to the Dictionary, "Cannula" means a flexible tube containing a trocar (sharp pointed end) that is used for aspiration or removal of fluids from cavities at one end that is inserted into a body cavity, duct, or vessel to drain fluid or administer a substance such as medication.

According to the Dictionary, "Catheter" means a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway. Its uses include the drainage of urine from the bladder through the urethra, or insertion through a blood vessel into the heart for diagnostic purposes.

Catheters are not used as piercing instruments, thus the catheters are not required to have a sharp tip.

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Applicants note that a big difference between a cannula and a catheter is the sharp end of the tip.

Applicants also note that in column 3, lines 28-33, the Schaer reference indicated that the shaft is overlapped with a jacket to prevent exposure of sharp metallic edges that can cause damage when the device is advanced through blood vessels. Thus, the reference is avoiding the use of sharp edges. The present invention requires a sharp tip to pierce the tissue.

Applicants note that the tip of the cited reference is not sharp, but rather dull, so that the vein through which it is advanced is not damaged. The tip of the reference is not designed for, or capable of, use for *piercing* of tissue.

In the field of anesthetic, the penetration, or piercing, essentially parallel to the nerve is required.

The cannula of the present invention exhibits a sharp tip, so that it can pierce tissue. The tip, which serves as an electrode, is not a separate part attached to the cannula tube, but is rather formed by the tip of the cannula tube itself.

Further, the structure of the cannula of the present invention allows the introduction of a catheter in case the anesthetic needs to be provided for a long period of time.

Now, if the inventor recognizes that a cannula and a catheter are two different devices that can be used together, can the Examiner indicate that a catheter is the same as a cannula?

Applicants also note that:

The Schaer reference teaches, in column 5, lines 5-6, that:

"All the strands forming the tubular member 15 need not be

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conductors; some may be formed of polymer materials such as nylon or Kevlar."

The reference also teaches that the shaft is formed of a plurality of individually insulated electrical conductors braided into the tubular member. (column 3, lines 5-8). Therefore, the tubular member is not electrically conductive. The electrical conductors attached to the tubular member are the ones that are electrically conductive.

Present Claim 12 requires an electrically conductive cannula tube formed by a steel tube; thus the Schaer reference does not teach the electrically conductive cannula tube as required by Claim 12.

Regarding point 4

Schaer does not teach a sharp tip for piercing, with only a very small, almost pinpoint area of the tip exposed.

The Schaer reference teaches, column 3, lines 26-32:

"A plastic jacket, preferably a lubricous polymer such as a thermoplastic fluoropolymer, Pebax or a polyethylene may be provided on the exterior of the shaft with a slight overlap of the jacket over the edges of the individual electrodes to prevent exposure of a sharp metallic edge which can cause damage when the elongated device is advanced through blood vessels."

Thus, the reference is not anticipating the present invention.

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

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Paragraphs 1-2 (Anticipation)

The Examiner rejects Claims 12-17 and 19-25 under 35 U.S.C. §102(b) as being clearly anticipated by Schaer (5,782,760). According to the Examiner, this reference teaches each and every element of the present claims, namely:

an electrically conductive cannula tube (11 and 51) with
a distal tip (53),
an exit opening (34),
a body part at the proximal end of the cannula,
an electrically insulting outer covering of the cannula tube, which extends from the body part out to the tip and which leaves the tip exposed at least in its distal end area and with

a connector (22) electrically connected to the cannula in the area of the body part,

wherein the body part includes an inlet opening axially aligned with the annular tube and wherein a conductor (16) runs through the casing of the body part to the circumference of the cannula tube.

Applicants respectfully traverse.

Applicants reviewed the reference and note that compared with amended Claim 12, the reference fails to teach: 1) a cannula; 2) an electrically conductive cannula tube formed by a steel tube; 3) a sharp tip; and 4) the tip is exposed at least in its distal end area.

Regarding points 1 and 3

In column 3, lines 28-33, the reference indicated that the shaft is overlapped with a jacket to prevent exposure of sharp

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metallic edges that can cause damage when the device is advanced through blood vessels. Thus, the reference is avoiding the use of sharp edges. The present invention requires a sharp tip to pierce the tissue.

According to the Dictionary, "Cannula" means a flexible tube containing a trocar (sharp pointed end) that is used for aspiration or removal of fluids from cavities at one end that is inserted into a body cavity, duct, or vessel to drain fluid or administer a substance such as medication.

According to the Dictionary, "Catheter" means a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway. Its uses include the drainage of urine from the bladder through the urethra or insertion through a blood vessel into the heart for diagnostic purposes.

Catheters are not used as piercing instruments, thus the catheters are not required to have a sharp tip.

Applicants note that a big difference between a cannula and a catheter is the sharp end of the tip.

Applicants note that the tip of the cited reference is not sharp, but rather dull, so that the vein through which it is advanced is not damaged. The tip of the reference is not designed for, or capable of, use for piercing of tissue.

In the field of anesthetic, the penetration, or piercing, essentially parallel to the nerve is required.

The cannula of the present invention exhibits a sharp tip, so that it can pierce tissue. The tip, which serves as an electrode, is not a separate part attached to the cannula tube,

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but is rather formed by the tip of the cannula tube itself.

As can be seen, a cannula has a completely different structure from a catheter.

Further, the structure of the cannula of the present invention allows the introduction of a catheter in case the anesthetic needs to be provided for a long period of time.

How, if the inventor recognizes that a cannula and a catheter are two different devices that can be used together, can the Examiner indicate that a catheter is the same as a cannula?

Regarding point 2

The Schaer reference teaches, in column 5, lines 5-6, that:

"All the strands forming the tubular member 15 need not be conductors; some may be formed of polymer materials such as nylon or Kevlar."

The reference also teaches that the shaft is formed of a plurality of individually insulated electrical conductors braided into the tubular member. (column 3, lines 5-8). Therefore, the tubular member is not electrically conductive. The electrical conductors attached to the tubular member are electrically conductive.

can be part of tubular member (i.e. rise compound)

Present Claim 12 requires an electrically conductive cannula tube formed by a steel tube; thus the Schaer reference does not teach the electrically conductive cannula tube as required by Claim 12.

Regarding point 4

Schaer does not teach a sharp tip for piercing, with only a

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very small, almost pinpoint area of the tip exposed.

The Schaer reference teaches, column 3, lines 26-32:

"A plastic jacket, preferably a lubricous polymer such as a thermoplastic fluoropolymer, Pebax, or a polyethylene may be provided on the exterior of the shaft with a slight overlap of the jacket over the edges of the individual electrodes to prevent exposure of a sharp metallic edge which can cause damage when the elongated device is advanced through blood vessels."

Thus, the reference is not anticipating the present invention.

Accordingly, withdrawal of the rejection is respectfully requested.

Paragraph 3 - (Obviousness)

The Examiner rejects Claim 18 under 35 U.S.C. §103(a) as being obvious over Schaer. According to the Examiner, Schaer discloses the invention substantially as claimed (see above). However, Schaer does not disclose that the exposed end area of the distal tip of the cannula has a length of maximally 1mm. Schaer, however, does disclose that a plastic jacket may be disposed about the distal shaft section, and holes may be made in the jacket to expose small portions of the underlying electrodes.

Applicants respectfully traverse for the same reasons set forth in paragraphs 1-2 and the following remarks:

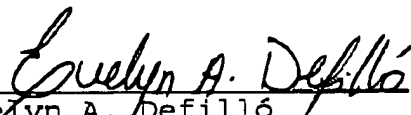
Claim 18 is novel in view of its dependency with novel Claim 12.

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Favorable consideration and early issuance of the Notice of Allowance is respectfully requested. The Examiner is respectfully requested to contact the undersigned so that a telephonic interview may be arranged.

Respectfully submitted,


Evelyn A. Defillo
Registration No. 45,630

PENDORF & CUTLIFF
P.O. Box 20445
Tampa, Florida
(813) 886-6085

Date: December 13, 2002

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CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing AMENDMENT B AND REQUEST FOR TELEPHONE INTERVIEW for U.S. Application No. 09/438,759 filed November 11, 1999, is being facsimile transmitted to the Patent and Trademark Office, "AFTER FINAL" facsimile number (703) 306-4520 Attn: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on December 13, 2002.

Evelyn A. Defillio

Name of Person Signing Certification

Evelyn A. Defillio
Signature

Dec 13/02
Date

AUTHORIZATION TO CHARGE

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

Evelyn A. Defillio
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VERSION WITH MARKINGS TO SHOW CHANGES MADE HEREBY ATTACHED

The Examiner is requested to accept the marked-up version as it is based on the previous version, which when modified as below, produces the clean version submitted with the current amendment.

IN THE CLAIMS:

Please amend the claims as follows:

12. (Once amended) A continuously conductive unipolar cannula for anesthesia, comprising:

an electrically conductive cannula tube (10) formed by a steel tube including a proximal end and a distal end, the distal end including a sharp tip (14) and an exit opening [(12, 44)] in the area of the sharp tip (14) dimensioned for passage of a catheter,

a body part (18) provided at the proximal end of the cannula tube (10), the body part (18) including an inlet opening (32, 34) axially aligned with the cannula tube (10) adapted for guiding [a] the catheter for introduction into the proximal end of the cannula tube (10), and

a connector (22, 24, 26) electrically connected to the cannula tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said cannula tube (10) has an electrically insulated outer covering extending from the body part (18) out to the sharp tip (14) and which leaves the sharp tip (14) exposed at least in its distal end area (16), and

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wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the cannula tube (10).

19. (Once amended) A continuously conductive unipolar cannula for anesthesia, comprising:

an electrically conductive cannula tube (10) formed by a steel tube including a proximal end and a distal end, the distal end including a tip (14) and an exit opening [(12, 44)] in the area of the tip (14) dimensioned for passage of a catheter,

a body part (18) provided at the proximal end of the cannula tube (10), the body part (18) including an inlet opening (32, 34) axially aligned with the cannula tube (10) adapted for guiding the catheter for introduction into the proximal end of the cannula tube (10), and

a connector (22, 24, 26) electrically connected to the cannula tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said cannula tube (10) has an electrically insulated outer covering extending from the body part (18) out to the sharp tip (14) and which leaves the sharp tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the cannula tube (10);

[A unipolar cannula according Claim 12,] wherein the distal tip (14) of the cannula tube (10) is a facet cut (12).

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PETITION FOR EXTENSION OF TIME

ATTORNEY DOCKET NO.: 2368.098

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing PETITION FOR EXTENSION OF TIME for U.S. Application No. 09/438,759 filed November 11, 1999, is being facsimile transmitted to the Patent and Trademark Office, "AFTER FINAL" facsimile number (703) 306-4520 Attn: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on December 13, 2002.

Evelyn A. Defilló

Name of Person Signing Certification

Evelyn A. Defilló
Signature

Dec 13/02
Date

AUTHORIZATION TO CHARGE

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

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